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**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
SAN FRANCISCO DIVISION**

UNITED STATES OF AMERICA; STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, AND WASHINGTON; THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA; AND THE DISTRICT OF COLUMBIA.

*ex rel.* ZACHARY SILBERSHER,

**Plaintiffs,**

V.

ALLERGAN, INC., ALLERGAN USA, INC.,  
ALLERGAN SALES, LLC, FOREST  
LABORATORIES HOLDINGS, LTD.,  
ADAMAS PHARMA, AND ADAMAS  
PHARMACEUTICALS, INC..

## Defendants.

Case No.: 3:18-cv-03018-JCS

**PLAINTIFF-RELATOR ZACHARY  
SILBERSHER'S OPPOSITION TO  
DEFENDANTS' MOTION TO  
CERTIFY ORDER FOR IMMEDIATE  
APPEAL AND FOR STAY (DKT. 136)**

Chief Magistrate Judge Joseph C. Spero

Hearing Date: February 5, 2021  
Time: 9:30 a.m.

Courtroom G, 15th Floor  
Phillip Burton Federal Building  
450 Golden Gate Avenue  
San Francisco, CA 94102

Action Filed: May 22, 2018

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1     **I. INTRODUCTION**

2         On December 11, 2020, the Court issued a 76-page Order (Dkt. 135) denying in their entirety  
 3 Defendants' motions to dismiss this False Claims Act (FCA) case. At the conclusion of oral argument,  
 4 the Court, after noting that discovery was stayed pending a decision on the motions, remarked: "If I  
 5 deny the motion[s], then I'll open discovery and we'll set a schedule and get it all done." (Dkt. 116 at  
 6 56:16-19.) Accordingly, in the same Order in which it denied Defendants' motions, the Court set a  
 7 Case Management Conference for the following month and directed the parties to submit a proposed  
 8 schedule for proceeding with the case. (Dkt. 135 at 76.)

9         Conspicuously absent from the 76-page Order was any indication that the Court, in working  
 10 through the public disclosure issues, had any inclination to put this action on hold so that the Ninth  
 11 Circuit might decide whether to accept an interlocutory appeal—a step that is reserved for “rare  
 12 circumstances,” is committed to the district court’s unfettered, unreviewable discretion to grant or  
 13 deny, and which “quite frequently” is summarily denied by the Ninth Circuit even in those exceptional  
 14 cases in which the district court grants permission to seek it. *James v. Price Stern Sloan, Inc.*, 283 F.3d  
 15 1064, 1067 n.6 (9th Cir. 2002).

16         Defendants nevertheless ask the Court to take the extraordinary step of certifying its Order for  
 17 interlocutory appeal because Defendants’ motions presented “‘difficult’ questions . . . which required  
 18 the Court to ‘grapple’ with the impact of the 2010 amendments to the FCA.” (Mot. at 1 (*citing*  
 19 Dkt. 135 at 32-33).) But interlocutory review is “not intended merely to provide review of difficult  
 20 rulings in hard cases.” *United States Rubber Co. v. Wright*, 359 F.2d 784, 785 (9th Cir. 1966). Instead,  
 21 Defendants bear the heavy burden of establishing that the Order presents a “controlling question of  
 22 law as to which there is substantial ground for difference of opinion and that an immediate appeal  
 23 from the order may materially advance the ultimate termination of the litigation.” 28 U.S.C. § 1292(b).

24         Defendants have failed to demonstrate that any ground for difference of opinion as to the  
 25 public disclosure bar issues here is “substantial.” Defendants point primarily to this Court’s  
 26 disagreement with *United States ex rel. Silbersher v. Valeant Pharm. Int’l, Inc.*, 445 F. Supp. 3d 393  
 27 (N.D. Cal. 2020) (“*Valeant*”)—specifically, with the *Valeant* court’s interpretation of the phrase

1 “Federal . . . hearing.” But as courts in this district have recognized, because an interlocutory appeal is  
 2 an “exceptional” case, “it would not warrant a § 1292(b) appeal simply because another district court  
 3 reached a different decision in a broadly similar case.” *Tsyn v. Wells Fargo Advisors, LLC*, 2016 WL  
 4 1718139, at \*4 (N.D. Cal. Apr. 29, 2016). Defendants’ arguments as to the purportedly “substantial”  
 5 ground for difference of opinion as to whether patent prosecution documents are “news media” or  
 6 “Federal reports” fare no better, which the Court’s clear rejection of the various nonbinding and  
 7 inapposite cases cited by Defendants demonstrates. (Dkt. 135 at 33-43.)

8 Defendants have also failed to show that an interlocutory appeal would be likely to materially  
 9 advance the ultimate termination of this litigation. This action has been pending for nearly three years,  
 10 and now that it is past the pleadings stage, this action can be ready for trial within the next 18 months.  
 11 An interlocutory appeal, which would certainly take at least one year and could very well take two  
 12 years or longer, would unnecessarily delay the case beyond the expected trial date absent such an  
 13 appeal. An interlocutory appeal would also not result in the ultimate termination of the case because  
 14 the Court’s public disclosure bar rulings are correct and in all likelihood will be affirmed. But even in  
 15 the unlikely event of a reversal, Relator is an original source under the statute, and the parties would  
 16 find themselves two years later litigating that issue (also possibly to an appeal), plus any additional  
 17 issues that Defendants may later decide to interject. This is why the rules contemplate a single appeal  
 18 after final judgment, instead of the piecemeal cycles of litigation and appeal that Defendants urge. The  
 19 Court should therefore deny Defendants’ request for certification and set a schedule that allows the  
 20 case to move forward expeditiously. *See Fed. R. Civ. P. 1.*

21 The Court should also deny Defendants’ fallback request for a stay pending the Ninth Circuit’s  
 22 decisions in *Valeant* and *United States ex rel. Integra Med Analytics LLC v. Providence Health & Servs.*,  
 23 2019 WL 3282619 (C.D. Cal. July 16, 2019). Defendants concede that, although *Valeant* and *Integra*  
 24 also deal with aspects of the public disclosure bar, it is quite possible the Ninth Circuit’s resolution of  
 25 those cases will have no bearing on this Court’s public disclosure rulings. (Mot. at 9.) And it is highly  
 26 unlikely that, even if the *Valeant* and *Integra* decisions do touch on public disclosure issues addressed  
 27 by this Court, they would require the Court to revisit its Order and revise its rulings, particularly since

1 neither of those cases deal with the specific questions that Defendants seek to certify here, *i.e.*,  
 2 whether “information reported by the PTO on its public Patent Application Information Retrieval  
 3 website (‘PAIR’) is a ‘Federal report,’” or whether “information published on the public version of  
 4 PAIR qualifies as ‘news media.’” (Mot. at 1.) And neither deal with the original source issue, which  
 5 would then have to be decided, even assuming for the sake of argument that *Valeant* and *Integra* lead  
 6 to directly applicable, adverse decisions. Defendants’ request for a stay pending the *Valeant* and  
 7 *Integra* decisions should therefore be denied.

## 8 **II. BACKGROUND**

9 Relator filed his initial Complaint on May 22, 2018 (Dkt. 1), and a First Amended Complaint  
 10 (“FAC”) on January 22, 2019 (Dkt. 12). The Allergan Defendants filed a motion to dismiss the FAC  
 11 on June 14, 2019 (Dkt. 63), and the Adamas Defendants filed a motion to dismiss on June 21, 2019  
 12 (Dkt. 68). On December 19, 2019, the Court heard oral argument on the motions to dismiss (*see* Dkt.  
 13 111), and on December 11, 2020, the Court issued a 76-page order denying the motions (Dkt. 135)  
 14 (the “Order”). The Court concluded that the “disclosures in the patent prosecution history” were “not  
 15 made through one of the channels specified in the current version of the public disclosure bar, which  
 16 therefore does not bar Relator’s claims.” (Dkt. 135 at 46.) Because the Court concluded that the public  
 17 disclosure bar had not been triggered, it did not reach the question of whether Relator is an original  
 18 source under the statute. (*Id.* at 46 n.17.)

19 With respect to the question of whether the disclosure of the patent prosecution documents at  
 20 issue was made through one of the three channels specified in the FCA, the Court thoroughly  
 21 addressed each of Defendants’ arguments in turn.

22 First, as to whether the documents constitute Federal reports, the court observed “it is  
 23 undisputed that patent prosecution is an *ex parte* administrative proceeding in which the Government  
 24 is not a party.” (Dkt. 135 at 33.) Following the Supreme Court’s instruction from *Schindler Elevator*  
*Corp. v. U.S. ex rel. Kirk*, 563 U.S. 401 (2011), that the FCA must be read as an “integrated whole,”  
 26 and applying well-established rules of statutory construction, the Court concluded that “the limitation  
 27 Congress added to romanette (i) of the public disclosure bar in 2010 would be all but eviscerated as to

any federal administrative matter if the Court were to adopt the broad reading of ‘Federal report’ urged by Defendants, as doing so would result in an interpretation under which *any* federal proceeding with a public docket – regardless of whether or not the Government was a party – would become a permissible channel that could trigger the public disclosure bar.” (Dkt. 135 at 33-34 (emphasis in original).) The Court rejected Defendants’ “reliance on a handful of cases in which courts purportedly found that comparable materials were ‘reports’ for the purposes of the FCA,” explaining that those cases, most of which applied the pre-2010 version of the public disclosure bar and were thus inapposite, were also readily distinguishable because the documents at issue in those cases differed markedly from the patent prosecution documents at issue here. (*Id.* at 36-40.)

Next, the Court addressed Defendants’ contention that “patent prosecution histories published on PAIR are not only ‘reports’ under the FCA but also ‘news media’” simply because they are available on the Internet. (Dkt. 135 at 41.) The Court declined to rely on the handful of mostly unpublished district court cases cited by Defendants, none of which attempted to ascertain the ordinary meaning of the term “news media” or to analyze the text of the statute. Instead, the Court agreed with the approach set forth by Judge Gutierrez in *United States ex rel. Integra Med Analytics LLC v. Providence Health & Servs.*, 2019 WL 3282619 (C.D. Cal. July 16, 2019) (“*Integra I*”). The Court concluded that “[c]ertainly, docket sheets such as PACER and PAIR do not fall within the meaning of the term ‘news media’ as it is ordinarily used.” (Dkt. 135 at 43.) The Court further determined that, “as Judge Gutierrez recognized in his discussion of PACER, interpreting ‘news media’ to include a public docket such as PAIR would be contrary to Congress’s intent when it amended the FCA’s public disclosure bar in 2010, as it would nullify the limitation Congress added to romanette (i) for the same reasons set forth above with respect to the term ‘Federal report.’” (*Ibid.*) The Court thus concluded that the documents at issue were not disclosed by the “news media.” (*Ibid.*)

The Court then turned to a contention that “neither set of Defendants argued in the original motion papers,” namely, that “the alleged fraud was disclosed in a ‘Federal . . . hearing’” within the meaning of the statute. (Dkt. 135 at 43-44.) The Court rejected that argument and “respectfully disagree[d] with the court’s reasoning in *Valeant*.” (*Id.* at 44.) The Court observed that the *Valeant*

1 court's interpretation of "Federal . . . hearing" is in "direct conflict with what Congress intended when  
 2 it amended the public disclosure bar in 2010." (*Ibid.*) The Court further noted that "the *Valeant* court's  
 3 interpretation of the term 'Federal . . . hearing' . . . results in . . . virtually total nullification of the  
 4 language that Congress added to romanette (i) of the public disclosure bar in 2010 as applied to any  
 5 federal proceeding." (*Id.* at 44-45.) The Court therefore concluded that the patent prosecution history  
 6 at issue in this case is not a Federal hearing under the current version of the statute. (*Id.* at 46.)

7 Having concluded that the public disclosure bar does not require dismissal of Relator's claims,  
 8 the Court turned to an analysis of whether Relator had stated a valid claim against Defendants under  
 9 the FCA. The Court concluded that Relator had adequately alleged false claims under theories of  
 10 promissory fraud as well as implied certification (Dkt. 135 at 63-71); that Relator adequately alleged  
 11 facts showing materiality (*id.* at 71-73); and that Relator adequately alleged scienter (*id.* at 73-74).

12 The Court did not indicate anywhere in its 76-page Order that it had any uncertainty regarding  
 13 its public disclosure rulings or other conclusions. Nor did the Court suggest that it believed the  
 14 extraordinary step of an interlocutory appeal was warranted to address any of the questions presented.  
 15 Accordingly, the Court denied Defendants' motions in their entirety; set a Case Management  
 16 Conference for January 15, 2021; and directed the parties to propose a schedule for the case.  
 17 (Dkt. 135.) The Court subsequently rescheduled the Case Management Conference for February 5,  
 18 2021, to coincide with the hearing on the instant motion. (*See* Dkt. 141.)

19 **III. ARGUMENT**

20 **A. The Court Should Decline to Certify the Order for Interlocutory Appeal**

21 **1. Interlocutory Appeal Is Reserved for Rare Circumstances**

22 In general, an appellate court should not review a district court ruling until after entry of final  
 23 judgment. *See* 28 U.S.C. § 1291. Because interlocutory appeal pursuant to 28 U.S.C. § 1292(b) is "a  
 24 departure from the normal rule that only final judgments are appealable," the statute "therefore must  
 25 be construed narrowly." *James v. Price Stern Sloan, Inc.*, 283 F.3d 1064, 1067 n.6 (9th Cir. 2002).  
 26 Interlocutory appeal is reserved for "rare circumstances," *ibid.*, and is to be "applied sparingly and  
 27 only in exceptional cases." *In re Cement Antitrust Litig.*, 673 F.2d 1020, 1025 (9th Cir. 1981), *cause*

1 *dismissed sub nom. Arizona v. U.S. Dist. Court for the Dist. of Arizona*, 459 U.S. 961 (1982), and *aff'd sub nom. Arizona v. Ash Grove Cement Co.*, 459 U.S. 1190 (1983). Use of immediate interlocutory appeals is “not intended merely to provide review of difficult rulings in hard cases.” *United States Rubber Co. v. Wright*, 359 F.2d 784, 785 (9th Cir. 1966).

5 Section 1292(b) gives the trial court discretion to certify a non-final decision for interlocutory  
 6 review, but only if all of the following statutory elements are met: (1) “the order involves a controlling  
 7 question of law,” (2) “as to which there is substantial ground for difference of opinion,” and (3) “an  
 8 immediate appeal from the order may materially advance the ultimate termination of the litigation.” 28  
 9 U.S.C. § 1292(b). The party pursuing the interlocutory appeal “bears the burden of establishing  
 10 § 1292(b)’s narrowly construed elements.” *United States ex rel. Mei Ling v. City of Los Angeles*, 2019  
 11 WL 6971061, at \*2 (C.D. Cal. Oct. 2, 2019) (*citing Coopers & Lybrand v. Livesay*, 437 U.S. 463, 475  
 12 (1978)).

13 The district court’s decision to certify an order for interlocutory appeal is entirely  
 14 discretionary; thus, “[e]ven when all three statutory criteria are satisfied, district court judges have  
 15 ‘unfettered discretion’ to deny certification.” *Heaton v. Soc. Fin., Inc.*, 2016 WL 232433, at \*2 (N.D.  
 16 Cal. Jan. 20, 2016) (*quoting Brizzee v. Fred Meyer Stores, Inc.*, 2008 WL 426510, at \*3 (D. Or. Feb.  
 17 13, 2008)). The district court’s certification decision is unreviewable. *See Exec. Software North Am., Inc. v. U.S. Dist. Court for Cent. Dist. of Cal.*, 24 F.3d 1545, 1550 (9th Cir. 2008), *overruled on other grounds by Cal. Dept. of Water Resources v. Powerex Corp.*, 533 F.3d 1087 (9th Cir. 2008).  
 18 Moreover, “[e]ven where the district court makes such a certification, the court of appeals nevertheless  
 19 has discretion to reject the interlocutory appeal,” which it does “quite frequently.” *James*, 283 F.3d at  
 20 1068 n.6 (citation omitted).

## 23           **2.       The Public Disclosure Issues are not Controlling Questions of Law**

24 It is not at all clear the first prong of the Section 1292(b) inquiry is satisfied. While the public  
 25 disclosure questions identified by Defendants are questions of law, they are not dispositive. A  
 26 resolution in Defendants’ favor might not advance the litigation at all because Relator could still be  
 27 deemed an original source under the statute (a question the Court did not reach). In that circumstance,  
 28

1 we would find ourselves exactly where we are now, after more than a year of additional delay. Thus,  
 2 these questions should not be deemed “controlling,” and Defendants’ request for interlocutory appeal  
 3 can be denied on this basis alone.

4                   **3. Defendants Have Failed to Establish Substantial Ground for Difference of  
                      Opinion as to the Public Disclosure Bar**

5

6                   “To determine if a ‘substantial ground for difference of opinion’ exists under § 1292(b), courts  
 7 must examine to what extent the controlling law is unclear.” *Couch v. Telescope Inc.*, 611 F.3d 629,  
 8 633 (9th Cir. 2010). Courts may find that substantial grounds for difference of opinion exist where  
 9 “the circuits are in dispute on the question and the court of appeals of the circuit has not spoken on the  
 10 point, if complicated questions arise under foreign law, or if novel and difficult questions of first  
 11 impression are presented.” *Ibid.* (citation omitted). Courts may find substantial ground for difference  
 12 of opinion as to novel issues “where reasonable jurists might disagree on an issue’s resolution, not  
 13 merely where they have already disagreed.” *Reese v. BP Expl. (Alaska) Inc.*, 643 F.3d 681, 688 (9th  
 14 Cir. 2011). However, “it would not warrant a § 1292(b) appeal simply because another district court  
 15 reached a different decision in a broadly similar case.” *Tsyn*, 2016 WL 1718139, at \*4 (*citing, inter  
                      alia, Spears v. Wash. Mut. Bk. FA*, 2010 WL 54755, at \*3 (N.D. Cal. Jan. 8, 2010) (“[T]hat one district  
 16 court came to a different conclusion on the same issue is insufficient to establish a substantial ground  
 17 for difference of opinion.”)). Just because “reasonable minds may differ” or “courts are reaching  
 18 different conclusions” as to the resolution of a particular issue, it does not necessarily follow that the  
 19 requirement of a “substantial” basis for a difference of opinion is satisfied. *DeLuca v. Farmers Ins.  
                      Exch.*, 2019 WL 4260437, at \*7 (N.D. Cal. Sept. 9, 2019); *see also Couch*, 611 F.3d at 633 (“just  
 20 because counsel contends that one precedent rather than another is controlling does not mean there is  
 21 such a substantial difference of opinion as will support an interlocutory appeal”).

22                   Defendants have failed to establish substantial grounds for difference of opinion regarding any  
 23 of the three public disclosure questions they identify.

24                   First, with respect to the Court’s determination that the patent prosecution documents at issue  
 25 do not constitute “Federal reports” under the current version of the public disclosure bar, Defendants

1 claim that the Court “departed from significant prior precedent.” (Mot. at 7.) Defendants do not cite  
 2 any of this supposedly “significant” precedent in their Motion, with good reason. As the Court  
 3 explained at length in the Order, Defendants rely “on a handful of cases in which courts purportedly  
 4 found that comparable materials were ‘reports’ for the purposes of the FCA,” yet “one of the cases  
 5 cited by Defendants . . . did not address the ‘report’ channel of disclosure at all,” and the remaining  
 6 cases, “most of which apply the pre-2010 version of the public disclosure bar,” concern other types of  
 7 documents that are readily distinguishable from the patent prosecution materials at issue here. (Dkt.  
 8 135 at 36-40.) Undeterred, Defendants cite back to their motion to dismiss briefing to contend that  
 9 “*Schindler* and its progeny provide ample authority” for their position. (Mot. at 8 (*citing* Dkt. 94 at 5-  
 10 7.) In doing so, Defendants completely ignore this Court’s thorough analysis and application of the  
 11 principles articulated in *Schindler* to the precise question of the meaning of “Federal report” as used in  
 12 the current version of the public disclosure bar. (Dkt. 135 at 33-36.) In short, Defendants have failed to  
 13 identify substantial grounds for difference of opinion as to whether documents publicly available on  
 14 PAIR constitute “Federal reports” under the public disclosure bar, and they merely regurgitate the  
 15 same arguments the Court has already rejected.

16 Second, with respect to the Court’s conclusion that the patent prosecution documents do not  
 17 constitute “news media” under the public disclosure bar, Defendants contend that the Court departed  
 18 from the “‘general consensus’ of the federal courts as to the broad meaning of the term ‘news media.’”  
 19 (Mot. at 7, *citing United States ex rel. Integra Med. Analytics LLC v. Providence Health & Servs.*,  
 20 2019 WL 6973547, at \*4 (C.D. Cal. Oct. 8, 2019) (“*Integra II*”).) While it is correct to say, as this  
 21 Court noted, that “numerous cases” have in the past interpreted the term “news media” broadly, it is  
 22 wrong to contend that anything resembling a “general consensus” exists for Defendants’ expansive  
 23 definition of news media as encompassing everything available on the Internet. Notably, in *Integra*,  
 24 Judge Gutierrez appears to have been the first jurist to “attempt[] to define the ordinary meaning of the  
 25 term ‘news media’ or to otherwise ground their interpretation in the statutory text,” *Integra I*, 2019  
 26 WL 3282619, at \*13, and Defendants have pointed to no decision post-*Integra* that has rejected Judge  
 27 Gutierrez’s analysis. And, as Judge Gutierrez noted, most of the prior cases to address the issue “did  
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1 not undertake their own independent analysis of the meaning and scope of the news media provision  
 2 and instead simply cited to previous decisions of other courts (that themselves often contained sparse  
 3 analysis) with little additional explanation.” *Ibid.* In other words, there has been no difference of  
 4 opinion, much less a substantial difference of opinion, when it comes to interpreting “news media”  
 5 based on its ordinary meaning and consistent with the overall text of the statute. *Cf. Tumampos v.*  
 6 *Cathay Pac. Airways Ltd.*, 2017 WL 10443170, at \*2 (N.D. Cal. June 30, 2017) (concluding that the  
 7 court’s “plain language analysis” of a statutory issue had “not been addressed squarely in any of the  
 8 decisions cited by the parties,” and that “[t]he Court’s analysis was new, and disputed by Defendant,  
 9 but this is not the type of extraordinary issue requiring interlocutory review”).

10 Furthermore, Defendants have failed to demonstrate that a substantial basis for a difference of  
 11 opinion exists as to either of the Court’s core conclusions on the particular question presented, *i.e.*,  
 12 whether the patent prosecution documents fall within the definition of “news media.” Specifically, the  
 13 Court concluded that “[c]ertainly, docket sheets such as PACER and PAIR do not fall within the  
 14 meaning of the term ‘news media’ as it is ordinarily used,” and that “interpreting ‘news media’ to  
 15 include a public docket such as PAIR would be contrary to Congress’s intent when it amended the  
 16 FCA’s public disclosure bar in 2010, as it would nullify the limitation Congress added to romanette  
 17 (i).” (Dkt. 135 at 43.) Defendants have not pointed to a single case that disagrees with either of these  
 18 fundamental conclusions, and Defendants cannot credibly argue that substantial ground exists that  
 19 warrants the exceptional step of certifying them for interlocutory review. Thus, although *Integra* has  
 20 been certified for interlocutory appeal, and while there may be room for disagreement as to the precise  
 21 scope and contours of the definition of “news media,” none of the authorities cited by Defendants  
 22 demonstrate a substantial basis for a difference of opinion as to the specific question for which  
 23 Defendants seek certification: “Whether information published on the public version of PAIR qualifies  
 24 as ‘news media’ as that term is used in Section 3730(e)(4)(A)(iii).” (Mot. at 1.) The Court’s statutory  
 25 construction is manifestly correct, and Defendants do not provide a persuasive reason to doubt it.

26 Third, with respect to “Federal hearing,” Defendants rely on an argument they never made in  
 27 their motion to dismiss papers, *i.e.*, that the patent prosecution history published on PAIR constitutes a  
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1 Federal hearing under romanette (ii) of the statute. Defendants argue that this Court’s disagreement  
 2 with *Valeant* demonstrates that “reasonable jurists . . . have already disagreed,” and therefore  
 3 substantial ground for difference of opinion exists. (Mot. at 7.) Defendants are correct that this Court’s  
 4 careful analysis of the statutory text and structure led it to disagree with the court’s reasoning in  
 5 *Valeant*. (Dkt. 135 at 43-45.) Yet, Defendants point to no case other than *Valeant* that has taken such  
 6 an expansive view of the phrase “Federal hearing,” and courts in this district have held that “it would  
 7 not warrant a § 1292(b) appeal simply because another district court reached a different decision in a  
 8 broadly similar case.” *Tsyn*, 2016 WL 1718139, at \*4; *Spears*, 2010 WL 54755, at \*3; *DeLuca*, 2019  
 9 WL 4260437, at \*7.

10 Accordingly, Defendants have failed to establish that substantial grounds for difference of  
 11 opinion exist that warrant the extraordinary measure of immediate interlocutory review of this Court’s  
 12 public disclosure rulings.

13 **4. Defendants Have Failed to Establish That Interlocutory Review of the Order  
 14 Will Materially Advance the Ultimate Termination of this Litigation**

15 There are “no set criteria a court is required to consider when evaluating whether an  
 16 interlocutory appeal will materially advance the litigation. Courts apply pragmatic considerations to  
 17 determine whether certifying non-final orders will materially advance the ultimate termination of the  
 18 litigation.” *Beeman v. Anthem Prescription Mgmt., Inc.*, 2007 WL 8433884, at \*2 (C.D. Cal. Aug. 2,  
 19 2007). Courts often find that the “likelihood of delay” weighs against certifying an interlocutory  
 20 appeal. *United States ex rel. Mei Ling v. City of Los Angeles*, 2019 WL 6971061, at \*5 (C.D. Cal. Oct.  
 21 2, 2019). “[E]ven when a trial date is not set, an appeal can still unnecessarily delay the termination of  
 22 the litigation.” *Ibid.* (*citing Andrews v. Plains All Am. Pipeline, L.P.*, 2017 WL 9831401, at \*5 (C.D.  
 23 Cal. Nov. 7, 2017)). Courts have counseled that an interlocutory appeal must be “likely to materially  
 24 speed the termination of the litigation.” *Allen v. ConAgra Foods, Inc.*, 2019 WL 1466889, at \*3 (N.D.  
 25 Cal. Feb. 6, 2019) (*quoting Ambrosio v. Cogent Commc’ns, Inc.*, 2016 WL 777775, at \*3 (N.D. Cal.  
 26 Feb. 29, 2016)).

1 Relator filed his initial Complaint in this case in May 2018, and the action has been pending  
 2 now for close to three years. An interlocutory appeal to the Ninth Circuit, which could take “upwards  
 3 of two years to be resolved,” would only serve to “further protract” this case. *Mei Ling*, 2019 WL  
 4 6971061, at \*5. Consistent with its duty to secure the “just, speedy, and inexpensive determination” of  
 5 the action, Fed. R. Civ. P. 1, the Court is poised to enter a scheduling order and set a trial date at the  
 6 upcoming case management conference. To that end, Relator has proposed a case schedule with an  
 7 anticipated trial date in July 2022, approximately 18 months from the date of the case management  
 8 conference. (See Dkt. 144 at 12-15.) Under the proposed schedule, it is likely that trial would take  
 9 place prior to the Ninth Circuit’s resolution of an interlocutory appeal. The anticipated delay resulting  
 10 from an interlocutory appeal thus counsels against certification here. See, e.g., *Shurance v. Planning*  
 11 *Control Int’l, Inc.*, 839 F.2d 1347, 1348 (9th Cir. 1988) (denying an interlocutory appeal that  
 12 “probably could not be completed” before the scheduled trial date); *Andrews v. Plains All Am.*  
 13 *Pipeline, L.P.*, 2017 WL 9831401, at \*5 (C.D. Cal. Nov. 7, 2017) (denying certification because “if an  
 14 interlocutory appeal were to move forward, then trial in this action would likely be delayed”).

15 Defendants claim that “[a]bsent a stay, the parties will soon begin a very burdensome  
 16 discovery process.” (Mot. at 8.) Discovery in this case will be no more burdensome than in other  
 17 similar cases. Defendants are also familiar with discovery in these types of cases in general and are  
 18 well-equipped to respond to the specific discovery issues they raise. The patent issues in this case have  
 19 already been subject to discovery in connection with prior proceedings, and the first phase of the  
 20 discovery here will simply require Defendants to produce what has already been produced in past  
 21 litigation. Moreover, many of the documents relating to Defendants’ scienter and scheme to protect the  
 22 chemical compound (memantine HCl) from generic competition—such as internal market erosion  
 23 analyses—would likely have already been produced in *In re Namenda IR Antitrust Litig.*, 1:15-cv-  
 24 07488-CM (S.D.N.Y.).<sup>1</sup> Finally, the district court in *In re: Restasis Antitrust Litigation*, Case No.  
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26 <sup>1</sup> Although that case involved different anticompetitive misconduct by Allergan through “product  
 27 hopping” from the “immediate release” version of Namenda to the extended-release version (Namenda  
 XR) relevant here, internal company documents relating to Allergan’s plans to protect the molecule from  
 generic competitors that were produced in the prior antitrust action would also be relevant here.

1:18-md-02819 (E.D.N.Y.), which involves allegations that Allergan fraudulently obtained patents to  
 2 protect their dry eye drug monopoly, required Allergan to engage in discovery at least as burdensome,  
 3 and likely far more so, than the anticipated discovery in this case, without interlocutory appeals or  
 4 unnecessary stays. Allergan is thus already quite familiar with identifying and producing the same  
 5 types of documents that will also be required in this case.

Defendants also assert there may be significant discovery required of government agencies,  
 such as their purchases or reimbursements for Namenda XR and Namzaric. But drug utilization,  
 purchase, and reimbursement data are already maintained by the relevant paying agencies. Exporting  
 such data for disclosure will not be unduly burdensome, especially since the Government is the  
 primary beneficiary that stands to recover billions of dollars in healthcare funds wasted as a result of  
 Defendants' unlawful misconduct. Such minor burden on the Government (especially compared with  
 the corresponding benefit) cannot justify delaying this case unnecessarily for years, while foreclosing  
 any possibility of settlement in the meantime. Indeed, the Government's purchase data and payment  
 decisions are relevant in virtually every *qui tam* action, and if Defendants' argument were accepted,  
 that potentially could cause many *qui tams* to be delayed through interlocutory appeals and stays.

In sum, an interlocutory appeal in this action is likely to significantly delay a case that has been  
 pending for nearly three years, and which in all likelihood could proceed to trial sooner than an  
 interlocutory appeal would be completed. In any event, the Court's Order is well-reasoned, correct,  
 and therefore likely to be upheld on appeal. Certification therefore is unlikely to materially advance  
 the termination of this case, and Defendants' motion should be denied.

## **B. The Court Should Decline to Stay This Action Pending an Interlocutory Appeal**

Whether to stay this case pending an interlocutory appeal is a matter committed to this Court's  
 sound discretion. "A stay is not a matter of right, even if irreparable injury might otherwise result."  
*Nken v. Holder*, 556 U.S. 418, 433–34 (2009) (*quoting Virginian R. Co. v. United States*, 272 U.S.  
 658, 672 (1926)). "It is instead 'an exercise of judicial discretion,' and '[t]he propriety of its issue is  
 dependent upon the circumstances of the particular case.'" *Nken*, 556 U.S. at 433-34 (*quoting*  
*Virginian R. Co.*, 272 U.S. at 672-673). The Supreme Court has articulated a four-factor test for

1 whether a stay should issue in any particular case: “(1) whether the stay applicant has made a strong  
 2 showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured  
 3 absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in  
 4 the proceeding; and (4) where the public interest lies.” *Nken*, 556 U.S. at 434. These factors are  
 5 measured under a “‘general balancing’ or ‘sliding scale’ approach, under which ‘a stronger showing of  
 6 one element may offset a weaker showing of another.’” *Stiner v. Brookdale Senior Living, Inc.*, 383 F.  
 7 Supp. 3d 949, 953 (N.D. Cal. 2019) (*quoting Leiva-Perez v. Holder*, 640 F.3d 962, 964 (9th Cir.  
 8 2011)).

9 As to the showing of likelihood of success on the merits, “if a movant is unable to show a  
 10 ‘strong likelihood of success,’ then the movant must at least demonstrate that the appeal presents a  
 11 ‘substantial case on the merits,’ or that there are ‘serious legal questions’ raised.” *Stiner*, 383 F. Supp.  
 12 at 953. Because courts in the Ninth Circuit take a “sliding scale” approach, a movant who can only  
 13 meet this “lower threshold” under the first factor “must then demonstrate that the balance of hardships  
 14 under the second and third factor tips *sharply* in the movant’s favor.” *Ibid.* (emphasis added); *Flo &*  
 15 *Eddie, Inc. v. Sirius XM Radio, Inc.*, 2015 WL 4397175, at \*3 (C.D. Cal. June 8, 2015). The moving  
 16 party “bears the burden of showing that the circumstances justify” a stay. *Stiner*, 383 F. Supp. 3d at  
 17 953.

18 Here, Defendants do not even attempt to argue they have a strong likelihood of success on the  
 19 merits. At most, Defendants contend that “there are serious questions on the merits here” which make  
 20 a stay appropriate. (Mot. at 11.) For the same reasons that Defendants have failed to establish there is  
 21 substantial ground for difference of opinion on the specific public disclosure questions at issue,  
 22 Defendants have not shown that there is a “serious question” on the merits warranting a stay. See  
 23 Section III(A)(3), *supra*, at 7-10. This factor weighs against the issuance of a stay.

24 As to the second and third factors, under the sliding scale approach, Defendants are required  
 25 not just to demonstrate “irreparable injury,” but that the balance of harms tips “sharply” in their favor.  
 26 They have failed to do so. Defendants speculate that discovery will be particularly expansive and  
 27 burdensome in this case, but there is no reason to believe discovery here will be any more burdensome

1 to Defendants than discovery in other complex litigation of its type, with which Defendants are  
 2 familiar and to which they are well-equipped to respond. On the other hand, a significant delay will  
 3 harm not just Relator, but the Federal and state governments on whose behalf this action is brought. As  
 4 the State of California recognized in its statement of interest (Dkt. 133), this action has major  
 5 importance for government health programs, not only because the government stands to recover  
 6 billions of dollars in fraudulent overcharges, but also because this action may set an important  
 7 precedent that would discourage similar overcharges resulting from the misuse of fraudulently-  
 8 obtained patents. Consequently, the significant delay Defendants seek could deprive the government  
 9 of a significant and much-needed financial recovery and delay the development of law that could help  
 10 curb drug-pricing abuse and expand affordable access to healthcare.

11 For the same reason, the public interest factor weighs against a stay. The public has a  
 12 significant interest in prompt resolution of cases, like this one, that “may help lower the price of  
 13 medicine and the cost of health insurance.” (Dkt. 133 at 3.) A lengthy stay of this action pending an  
 14 interlocutory appeal, which would likely last at least a year, and possibly even two years or more,  
 15 would not just delay trial, but would also be likely to significantly delay the chances of a settlement,  
 16 which is the means by which most cases are resolved. For example, Allergan settled *In re Namenda IR*  
 17 *Antitrust Litig.* for \$750 million before trial, *see* 1:15-cv-07488 (S.D.N.Y.), at Dkt. 947—avoiding the  
 18 need for any appeals whatsoever. Had there been an interlocutory appeal or a stay in the *Namenda IR*  
 19 *Antitrust Litig.* when the defendants initially lost their motions to dismiss, that case would likely not  
 20 have settled and would probably still be in litigation today. Thus, in the event this Court certifies its  
 21 Order for interlocutory appeal, it should exercise its discretion to decline to stay the case.

22 **C. The Court Should Decline to Stay This Action Pending the Resolution of the Ninth  
 Circuit Appeals in the *Valeant* and *Integra* Cases**

23 The pending appeals in *Valeant* and *Integra* do not warrant a stay of this case. In determining  
 24 whether to exercise its discretion to “stay proceedings pending disposition of another case that could  
 25 affect the outcome,” the Court “must balance the length of the delay against the justifications for the  
 26 stay.” *Asis Internet Servs. v. Active Response Grp.*, 2008 WL 4279695, at \*4–5 (N.D. Cal. Sept. 16,  
 27 2008) (*citing* *Yong v. INS*, 208 F.3d 1116, 1119 (9th Cir. 2000)). Specifically, the Court should weigh  
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1 “(1) the possible damage which may result from the granting of a stay, (2) the hardship or inequity  
 2 which a party may suffer in being required to go forward, and (3) the orderly course of justice  
 3 measured in terms of the simplifying or complicating of issues, proof, and questions of law which  
 4 could be expected to result from a stay.” *Phan v. Transamerica Premier Life Ins. Co.*, 2020 WL  
 5 5576358, at \*2 (N.D. Cal. Sept. 17, 2020) (*quoting CMAX, Inc. v. Hall*, 300 F.2d 265, 268 (9th Cir.  
 6 1962)). The moving party bears the burden of establishing a need for a stay. *Ibid.* (*citing Clinton v.*  
 7 *Jones*, 520 U.S. 681, 708 (1997)). A stay of indefinite duration requires the moving party to  
 8 demonstrate a “pressing need.” *Landis v. N. Am. Co.*, 299 U.S. 248, 255 (1936).

9 Defendants request an indefinite stay of this action pending the Ninth Circuit’s resolution of  
 10 the *Valeant* and *Integra* appeals. They do not articulate any “pressing need” for this stay; their only  
 11 argument is that “the Ninth Circuit’s analysis in both cases may be of valuable assistance to this Court  
 12 in considering Defendants’ public-disclosure-bar defenses,” and that “[b]oth cases will clarify the  
 13 scope and meaning of the public disclosure bar after the 2010 amendments and could alter this Court’s  
 14 analysis of the issues presented by Defendants’ motions to dismiss.” (Mot. at 12-13.) Yet Defendants  
 15 have acknowledged there is a very good chance the Ninth Circuit’s decisions in *Valeant* and *Integra*  
 16 will not affect this Court’s analysis of the specific public disclosure bar questions at issue here. (*See*  
 17 Mot. at 9 (“it is possible the Ninth Circuit will decide *Valeant* without addressing one of the core  
 18 controlling questions of law presented here,” and that “the Ninth Circuit’s *Integra* decision will  
 19 announce a rule for private websites, but not Government ones”<sup>2</sup>).) Thus, while the Ninth Circuit’s  
 20 forthcoming decisions undoubtedly will address the scope of the public disclosure bar in general, it is  
 21 highly speculative whether either of those decisions will require the Court to reverse any of its key  
 22 conclusions, such as whether patent prosecution documents fall within one of the enumerated channels  
 23 of the statute. To the contrary, the likely outcome is that the Ninth Circuit’s resolution of *Valeant* and  
 24 *Integra*—even if they provide additional clarity around the public disclosure bar—will not change the

26 \_\_\_\_\_  
 27 <sup>2</sup> *Integra* is also unlikely to lead to a directly applicable holding, even if the Ninth Circuit reverses,  
 because the issue relating to nullification of Congress’s 2010 amendments to 31 U.S.C.  
 § 3730(e)(4)(A)(i) is not squarely presented in *Integra* as it is here.

1 outcome in this case. A stay is thus unlikely to “simplify[]” the specific “questions of law” this Court  
 2 has already thoroughly addressed. *Phan*, 2020 WL 5576358, at \*2 (*quoting CMAX*, 300 F.2d at 268).

3 Moreover, given Defendants’ view that “the Ninth Circuit will weigh in on both cases within a  
 4 reasonable time period” (Mot. at 13), any burden to Defendants of proceeding with discovery between  
 5 now and then will be relatively low. In the unlikely event that *Valeant* or *Integra* requires this Court to  
 6 revisit its public disclosure rulings, the Court could do so in short order. The hardship or inequity  
 7 Defendants might face in being required to go forward at this juncture is therefore minimal. By  
 8 contrast, Relator and the federal and state governments have an interest in the prompt recovery of the  
 9 overcharges incurred by them, and a stay of even a few months would delay any such recovery, with  
 10 little prospect that such a delay would have made make any difference at all. The orderly course of  
 11 justice weighs in favor of continuing to move this case forward, rather than staying it indefinitely.

12 The most efficient course, therefore, is to proceed expeditiously with this matter, consistent  
 13 with the principle underlying Rule 1 of the Federal Rules of Civil Procedure that provides for the “just,  
 14 speedy, and inexpensive” adjudication of Relator’s claims.

15 **IV. CONCLUSION**

16 For the foregoing reasons, the Court should deny Defendants’ motion in its entirety.

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Respectfully submitted,

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